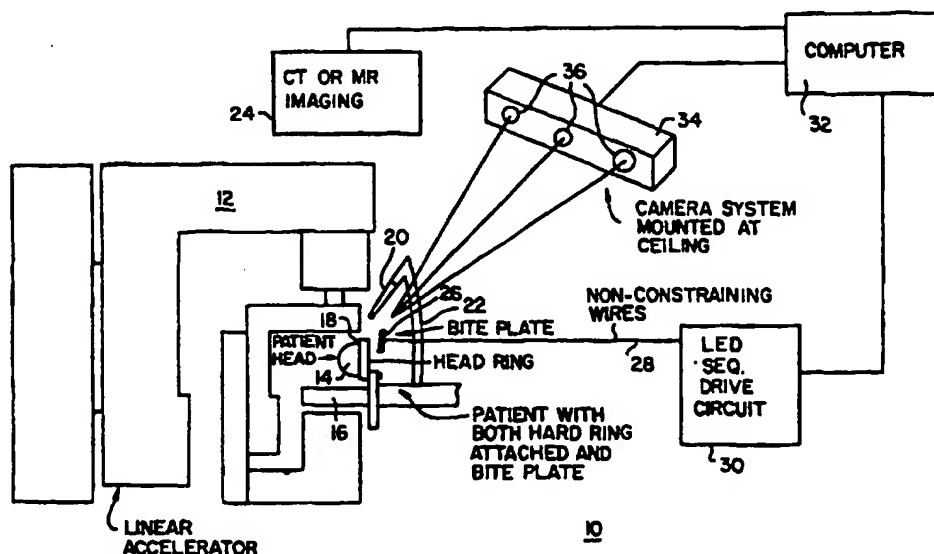




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(54) Title: REPEAT FIXATION FOR FRAMELESS STEREOTACTIC PROCEDURE



(57) Abstract

Repeat fixation for medical procedures is accomplished using a non-invasive locator, specifically a bite plate (26). The bite plate (26) has at least three fiducial markers (38) on it. The fiducial markers (38) may be LEDs, radiopaque markers for angiography or computerized tomography (CT) imaging or magnetic resonance markers for magnetic resonance (MR) imaging. By detecting the position of the markers (38), the position of features within the patient (14) (such as a brain tumor or other intracranial target to which radiation is to be applied) can be determined with great precision. Since the bite plate (26) has been molded to uniquely fit to the patient's teeth, it may be removed after an initial imaging of the patient (14). The bite plate (26) may then be re-attached one or more times to the teeth and the location of the features will be in a known position relative to the sensed markers.

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REPEAT FIXATION FOR FRAMELESS STEREOTACTIC PROCEDUREBackground of the Invention

The present invention relates to device, system and method for stereotactic medical procedures. More specifically, it provides for repeated accurate positioning (fixation) of a patient or part of a patient for carrying out medical procedures which are done at different times.

Various medical procedures involve repeated treatments at different times. For example, application of radiation is sometimes used for treating brain tumors or other conditions. Although a single application of radiation may sometimes be used, under many circumstances there are sound medical reasons to use repeated application of radiation at different times.

The treatment of a radiation therapy patient can be broken down into four stages. These are (1) diagnostic evaluation, (2) treatment planning, (3) simulation and (4) treatment. Our repeat fixation device is applicable to the latter three phases of the treatment process. In the first stage of diagnostic evaluation the physician decides which tissues are at risk of disease and should be targeted. The patient may undergo many diagnostic tests including angiography, computerized tomography (CT) and magnetic resonance (MR) imaging. After the physician is satisfied that they have identified the tissues at

risk, the patient then undergoes a process known as treatment simulation. This process involves obtaining a set of images such as plane films, digital images, CT, MRI, and ultrasound images. These radiographs allow the physician to select a specific path for each radiation beam which only includes the tissues at risk and excludes normal tissues. Because the tissues the physician has targeted are often radiographically transparent the physician routinely relies upon radiographic landmarks to infer the proper beam alignment. These same landmarks are subsequently imaged on similar radiographs taken with the therapeutic x-ray beam prior to administering the radiation treatment. These pretreatment radiographs, which are known as therapy portal films, allow the physician to judge the appropriate alignment of the treatment beam and the patients anatomy. The frequency at which these portal films are repeated is dependent upon the complexity of the patient setup and the proximity of the beam to critical structures (such as a patient's optic nerve).

A routine course of radiation therapy may span anywhere from 10 to 64 fractions over a period of two to six weeks. The number of treatments dependent upon the specifics of the particular disease. For each fraction

the patient must be repositioned at the teletherapy unit and aligned relative to the radiation beam.

There exists a clinical situation in which the target tissues cannot be adequately localized by their proximity to radiographically opaque structures as required by the above simulation procedure.

Arteriovenous malformations, acoustic neurinomas and other small intracranial targets are examples of such clinical entities. To enable the identification, and subsequent treatment of such targets, a new and very powerful technique known as radiotherapy has been developed. (Radiosurgery is usually considered to be a single fraction radiotherapy treatment, meaning a single treatment, although it may also be more broadly interpreted. Multiple radiotherapy treatments are often called high precision radiotherapy or fractioned stereotactic radiotherapy.) This technique allows small intracranial targets to be identified and treated to a very high degree of precision.

The radiosurgical technique uses stereotactic principles for targeting, localization and treatment. The procedure begins with a stereotactic reference system being fixed to the patient's skull. This reference system remains fixed relative to all intracranial points throughout the entire radiosurgical procedure. All

diagnostic exams, such as angiography, CT and MR scanning include a set of fiducial markers which allow all points within the image to be localized relative to the stereotactic reference frame.

5 Once the target tissues have been identified the path of radiation beams can be mathematically computed. The computer algorithms, which support this procedure, allow the clinician to evaluate the amount of dose which would be deposited within the patient if the simulated
10 beams were actually x-ray beams were applied along the proposed paths. In an attempt to arrive at a treatment plan which adequately confines the radiation dose to the target tissues while limiting the dose to all normal tissues the beams of radiation are modified, eliminated
15 or new beams added to the plan. Once a plan with an acceptable dose distribution has been arrived at the information on beam trajectory is transferred to the radiotherapy treatment unit. A single fraction of radiation is then given to the patient and the
20 stereotactic frame is removed. The entire length of the procedure, from frame application through treatment, usually spans 6 to 8 hours.

 The present inventors' prior U.S. patents listed below, assigned to the assignee of the present
25 application and hereby incorporated by reference disclose

techniques for providing stereotactic radiosurgery with a high degree of precision:

	<u>U.S. Patent</u>	<u>Issue Date</u>	<u>Title</u>
5	5,027,818	July 2, 1991	DOSIMETRIC TECHNIQUE FOR STEREOTACTIC RADIOSURGERY
	5,189,687	February 23, 1993	APPARATUS FOR STEREO- TACTIC RADIOSURGERY

The techniques of the inventors' above patents allow the patient to be precisely positioned relative to radiation beams of stereotactic radiosurgery to within 0.2 mm plus or minus 0.1 mm. Although this works very well for single fraction therapy, there exist clinical settings where fractionating the total dose, i.e. dividing the dose into many small fractions, would yield additional therapeutic advantage. In the radiotherapy procedure, once the reference frame has been removed from the patient the relationship between intracranial target points and the reference system is lost. Because the above procedure would require the reference frame to remain fixed to the patient's skull through the entire course of treatment, which may last several weeks, this approach is considered inappropriate for fractionated therapy. Alternately, each fractional treatment would require a laborious and time-consuming procedure to re-

determine patient position for second and subsequent treatments.

There exist several different techniques for non-invasive repeat fixation. These methods can be broken
5 down into three basic categories. These are bite plate systems, contour realignment systems and mask systems. All of these systems have design flaws which can lead to unacceptable, and undetectable, positional errors.

The mask techniques have been used in radiation
10 therapy for over three decades. In these system a custom mask, which snugly fits either the face or the entire head, is fabricated. For high precision radiotherapy the mask is then attached to a stereotactic reference frame, similar to the frame used for any stereotactic procedure.
15 Prior to each diagnostic exam the patient is placed into the mask/frame system and normal stereotactic fiducial systems are used for image registration.

Mask immobilization and repositioning systems have been used extensively in radiation therapy. From
20 multiple reports in the literature mask systems appear to have a repeat fixation tolerance no better than 3 to 5 mm. It is our opinion that this level of accuracy is unacceptable for fractionated radiotherapy.

Bite plate systems have also been used in
25 radiotherapy for several decades. This technique

requires the fabrication of a customized bite plate. The plate fits snugly onto the patient's teeth. As with the mask/frame systems, the bite plate is fixed to a stereotactic reference frame which then accepts the

5 routine set of fiducial markers for both plane film radiography, CT and MR scanning. The primary disadvantage of this system is that the bite plate is used for both localization and patient fixation. The bite plate not only provides the reference for

10 stereotactic localization, but it also is the mechanism which is used to move the patient into position. Moving the patient by use of the bite plate produces torque on the bite plate-teeth interface. An analysis of this approach reveals that very small movements in the bite

15 plate position, relative to the patient's teeth, can result in large translations and rotations of the intracranial targets. Since no method of alignment verification has ever been developed, these errors go undetected.

20 An alternate system for patient positioning uses the patient's own anatomical contours as the stereotactic reference system. In this approach a CT or MR scan is taken and a three dimensional reconstruction of the patient's surface is obtained. These contours act as the

25 reference system for stereotactic localization.

The usual diagnostic exams are carried out and the treatment is then planned using the same stereotactic principles used in routine radiotherapy. The target is identified and the patient's surface contour coordinates are measured relative to the isocenter. The patient is placed at the teletherapy treatment unit and the surface contours are again obtained through the use of surface digitization. A set of algorithms then calculate the translations as well rotations required to reposition the patient's target over the teletherapy units isocenter. The accuracy of such systems under clinical test conditions have been shown to be approximately two to three mm.

When performing fractionated radiotherapy, accuracy in applying the radiation is very important. Some tumors or other conditions require that the radiation be concentrated in relatively small volumes. Misalignment of the radiation beam may cause an insufficient amount of radiation to be applied to the tumor or other target. Further, such misalignment may increase the likelihood and/or degree of damage to healthy tissue adjacent the tumor or other target.

Fractionated radiotherapy may be imprecise if the tumor or other target cannot be localized with a sufficient degree of accuracy. However, this need for

proper localization is the same need which one has when performing single dose radiotherapy and this need is addressed by the present inventors' incorporated by reference patents. The additional factor in fractionated radiotherapy is the need to easily and accurately repeat a position of the patient. If the position of the patient was accurate relative to the first treatment, the repositioning should normally cause the patient to assume the exact same position (relative to the treatment mechanism) for the second and subsequent treatments. However, if the second or other subsequent treatment is performed with the patient only slightly moved from the first treatment position, this will introduce inaccuracies. The repeat fixation techniques discussed above have the indicated disadvantages.

More generally, the need for repeat fixation of a patient or portion of a patient exists outside of radiotherapy. In the general case, one wishes to perform a first medical procedure on a patient with a precise localization of portions of the patient, and, at some later time, perform a second medical procedure on the patient with a precise localization of portions of the patient. One can repeat laborious and time-consuming localization steps for the second medical procedure, but this increases medical costs and complexity. As used

herein, a medical procedure is a procedure for diagnostic and/or remedial purposes.

Objects and Summary of the Invention

Accordingly, it is a primary object of the present
5 invention to provide a new and improved method and system for repeat fixation in performing medical procedures.

A more specific object of the present invention is to provide for highly precise non-invasive repeat fixation.

10 A further object of the present invention is to provide repeat fixation in which a locator is mechanically independent from any structures used for positioning the patient. That is, any structure used to position the patient does not move the locator except by
15 way of the patient.

Yet another object of the present invention is to provide repeat fixation for stereotactic radiotherapy.

A further object of the present invention is to provide repeat fixation which allows relatively fast re-
20 localization of a patient after an initial localization.

Yet another object of the present invention is to provide repeat fixation which minimizes or avoids the disadvantages of prior techniques discussed above.

The above and other features of the present invention which will be more readily understood when the following detailed description is considered in conjunction with the accompanying drawings are realized
5 by a medical method including the steps, not necessarily in order, of: positioning a patient for a first medical procedure; and attaching a mechanically free locator to a patient, the locator having at least 3 LEDs (light emitting diode) thereon and being in registry with a
10 portion of the patient. As used herein, a mechanically free locator is one which is used for localization without being rigidly fixed to a structure other than possibly a portion of a patient. LEDs are used a first time to get precise positioning information relative to
15 at least part of the patient.

A first medical procedure is performed on the patient. After the first medical procedure, the locator is removed from the patient. At a later time, the locator is re-attached to the patient, the locator again
20 being in registry with the portion of the patient and having an identical orientation relative to the portion of the patient as when the locator was previously attached. After the re-attaching step, the LEDs are used a second time to get precise positioning information
25 relative to the at least part of the patient. After the

re-attaching step, a second medical procedure is performed on the patient.

Preferably, the attaching and re-attaching of the locator is non-invasive. As used herein, non-invasive
5 shall mean that no holes need to be created in a patient and no patient tissue needs to be removed in order to attach and re-attach the locator.

More specifically, the locator is a bite plate with an external portion connected thereto, and the LEDs are
10 on the external portion. The attaching includes using a mold of dental impression material to bring the bite plate in registry with teeth of the patient, and wherein the re-attaching uses the mold to bring the bite plate in
15 registry with teeth of the patient with an identical orientation relative to the teeth as when the bite plate was previously attached.

In one technique of the invention, the first medical procedure is an imaging of at least a portion of the patient and the second medical procedure is a remedial
20 procedure treating at least one problem precisely localized in the first medical procedure. The second medical procedure may use a probe inserted in the patient for treatment of the patient or the second medical procedure includes radiotherapy.

In another aspect of the invention, both the first and second medical procedures include radiotherapy.

The using of the LEDs the first and second times utilizes a sensing subsystem for sensing the positions of the LEDs. Before performing the second medical procedure, the patient is positioned using a positioner independent of the locator to secure at least the portion of the patient in a desired position.

The present invention may alternately be described as a system for medical procedures, the system including a locator attachable to a patient, having at least 3 LEDs thereon, and having a registration portion for registration with a portion of a patient's body. The registration portion allows removal of the locator from the patient and re-attachment to the patient with an identical orientation relative to the portion of the patient as when the locator was previously attached. The locator is mechanically free such that a patient is positionable without applying forces to the locator during patient positioning. The system has a positioner independent of the locator and operable to secure at least the portion of the patient in a desired position. A sensing subsystem is operable for sensing the positions of the LEDs when the patient is in the desired position. The locator is non-invasive. The locator is more

specifically a bite plate with an external portion connected thereto, and the LEDs are on the external portion, and the bite plate has dental impression material for fabrication of a mold to bring the bite plate in registry with teeth of the patient, and the mold is operable to bring the bite plate in registry with teeth of the patient with an identical orientation relative to the teeth as when the bite plate was previously attached.

10 The system further includes a radiotherapy apparatus for applying radiation treatment to a patient, the positioner and sensing subsystem allowing proper positioning of the patient for applying radiation treatment. The system further includes an imaging
15 subsystem for imaging the patient.

 The present invention may further be described as a medical method comprising the steps, not necessarily in order, of: positioning a patient for a first medical procedure; attaching a locator to a patient, the locator
20 having at least 3 fiducial markers thereon and being in registry with a portion of the patient; using fiducial markers a first time to get precise positioning information relative to at least part of the patient; and performing a first medical procedure on the patient.
25 After the first medical procedure, the locator is removed

from the patient. At a later time after the removal of the locator, the locator is re-attached to the patient, the locator again being in registry with the portion of the patient and having an identical orientation relative to the portion of the patient as when the locator was previously attached. After the re-attaching step, fiducial markers are used a second time to get precise positioning information relative to at least part of the patient. After the re-attaching step, a second medical procedure is performed on the patient. The locator is a bite plate with an external portion connected thereto, and the fiducial markers are on the external portion, and wherein the attaching includes using a mold of dental impression material to bring the bite plate in registry with teeth of the patient. The re-attaching uses the mold to bring the bite plate in registry with teeth of the patient with an identical orientation relative to the teeth as when the bite plate was previously attached.

In one technique, the first medical procedure is an imaging of at least a portion of the patient and the second medical procedure is a remedial procedure treating at least one problem precisely localized in the first medical procedure. The second medical procedure uses a probe inserted in the patient for treatment of the

patient or the second medical procedure includes radiotherapy.

In another technique of the invention, both the first and second medical procedures include radiotherapy.

5 In a specific aspect of the invention, the fiducial markers used the first time are objects other than LEDs and the fiducial markers used the second time are LEDs put on the external portion at locations of the objects.

In an alternate specific aspect of the invention,
10 the fiducial markers used the first and second times are LEDs and the using of the fiducial markers the first and second times utilizes a sensing subsystem for sensing the positions of the LEDs. Before performing each of the first and second medical procedures, the patient is
15 positioned using a positioner independent of the locator to secure at least the portion of the patient in a desired position.

The present invention may alternately be described as a system for medical procedures, the system including
20 a locator attachable to a patient, having at least 3 fiducial markers thereon, and having a registration portion for registration with a portion of a patient's body, the registration portion allowing removal of the locator from the patient and re-attachment to the patient
25 with an identical orientation relative to the portion of

the patient as when the locator was previously attached,
the locator being mechanically free such that a patient
is positionable without applying forces to the locator
during patient positioning. A positioner is independent
5 of the locator and operable to secure at least the
portion of the patient in a desired position. A sensing
subsystem senses the positions of the fiducial markers
when the patient is in the desired position. In a
specific aspect of the invention, the locator is a bite
10 plate with an external portion connected thereto, the
fiducial markers are on the external portion, and the
bite plate has a mold to bring the bite plate in registry
with teeth of the patient, and the mold is operable to
bring the bite plate in registry with teeth of the
15 patient with an identical orientation relative to the
teeth as when the bite plate was previously attached.

The system may further include a radiotherapy
apparatus for applying radiation treatment to a patient,
the positioner and sensing subsystem allowing proper
20 positioning of the patient for applying radiation
treatment. A radiotherapy apparatus configured for
radiosurgery, a standard linear accelerator, a
radiosurgery apparatus as described in the above prior
patents, and any other device for applying therapeutic

radiation would be considered a radiotherapy apparatus as the term is used herein.

The fiducial markers includes three LEDs which uniquely define a plane.

5 Brief Description of the Drawings

The above and other features of the present invention will be more readily understood when the following detailed description is considered in conjunction with the accompanying drawings wherein like
10 characters represent like parts throughout the several views and in which:

FIG. 1 is a simplified diagram of the system of the present invention;

FIG. 2 is an enlarged side view of a patient's head
15 with portions of the present invention attached thereto;

FIG. 3 is a detailed view of locator according to the present invention; and

FIG. 4 is an exploded view of the locator of FIG. 3.

Detailed Description

20 The system 10 of the present invention is shown in FIG. 1 as having a linear accelerator 12 for performing stereotactic radiotherapy on a patient's head 14 which is

on a surgical table 16 (shown only partially) and secured thereto by way of a head ring 18. The details of the accelerator 12 and table 16 are not a necessary part of the present invention and need not be discussed.

5 Moreover, these would be constructed and operable in the manner discussed with respect to the structures and techniques of the above incorporated by reference U.S. Patents of the inventors, this allowing the precision application of radiotherapy to the patient.

10 As an alternative or additionally to the accelerator 12, a probe 20 (constructed in known fashion) for stereotactic surgery may be mounted to anchor 22 secured to the table 16 as shown or to a wall or other structure such as a linear accelerator, CT, MR, or any other
15 reference required (not shown). The probe 20, which is a scalpel, laser, or other surgical apparatus, may alternately have LEDs thereon for sensing the exact position and direction (orientation) of the probe in space using known techniques such that the probe need not
20 be attached to anything.) A further alternative or additional feature may be an imaging system such as computerized tomography (CT) or magnetic resonance (MR) system 24. One or more of the accelerator 12, probe 20, and imaging system 24 are used to perform medical
25 procedures on the patient.

The present invention provides for repeated fixation of a locator in registry with (i.e., uniquely positioned relative to) a portion of a patient. Before discussing details of how this is accomplished, it will generally be
5 noted that the locator is used to provide a frame of reference for performing a first medical procedure and the locator is then removed. The locator is then re-attached to the patient such that a second medical procedure could be performed. The medical procedures may
10 be any diagnostic and/or treatment procedures. However, the discussion which follows will emphasize use of the technique for fractionated stereotactic radiotherapy.

The present system uses a bite plate 26 connected by non-constraining (i.e., they are loose and do not
15 significantly pull on the bite plate) wires 28 to an LED sequential drive circuit 30. (In lieu of the wires, a wireless arrangement, not shown, could be used to strobe the LEDs or a drive circuit could be on the bite plate itself.) Circuit 30 is also connected to a computer 32.
20 The computer is connected to the imaging system 24 and a camera system 34. The camera system 34, which serves as a sensing subsystem, may be of a known type having several cameras 36 as part thereof in order to locate the bite plate 26 by way of several LEDs (not shown in FIG.
25 1) thereon. The camera system 34 and technique for

strobing the LEDs (sequentially lighting them one at a time) may be that disclosed in U.S. Patent 5,198,877, issued to Schulz on March 30, 1993, assigned on its face to PixSys, Inc, and hereby incorporated by reference.

5 Such a camera system is commercially available from PixSys, Inc.

With reference now to FIG. 2, the patient's head 14 is restrained and can be positioned by use of a head ring 18, which ring would then be fixed in place using
10 techniques discussed in the present inventors' incorporated by reference patents. The head ring 18 may be of any type used or developed to constrain the head.

The bite plate 26 is a type of locator and has at least three LEDs 38 (only two visible in FIG. 2) thereon.
15 The three LEDs are not in a line and therefore uniquely define a plane. Most advantageously, the bite plate 26 is mechanically free such that a patient is positionable without applying forces to the locator during patient positioning. The bite plate 26 is more specifically
20 independent any structures (such as ring 18) used for positioning the patient (such structures being called positioning structures). That is, any structure used to position the patient does not move the bite plate 26 except by way of the patient. In that fashion, no forces
25 or torques are applied to the bite plate 26 which might

cause it to slightly change its position relative to the patient.

With reference to FIGS. 3 and 4, the bite plate 26 has a plastic mouth portion 39 having tooth imprints 40 (only a few shown for ease of illustration) previously formed of dental mold material on mouth portion 38 in known fashion. A mount plate 42 is integral with or fixed to mouth portion 39. Three holes 44 are disposed within the mount plate 42 and allow it to removably receive a marker plate 46 having three posts 48 mating to the holes 44. The marker plate 46, which is planar and parallel to the likewise planar mount plate 42, can be constructed of transparent plastic and have LEDs 38 disposed therein (as shown) or mounted on a surface thereof.

An alternate marker plate 50, shown in FIG. 4 only, may be shaped the same as marker plate 46 and have three posts 52 (only one visible) for securing it to the mount plate 42 by way of holes 44. Instead of using LEDs as fiducial markers, marker plate 50 has three markers 54 which may be radiopaque markers for angiography or CT scanning or which may be magnetic resonance markers for MR scanning. Only two of the markers 54 are visible in FIG. 4, but it will be appreciated that their placement

and positioning would preferably be the same as shown for LEDs 38 in FIG. 3.

Considering now all of the FIGS., the operation of the invention for fractionated stereotactic radiotherapy will be discussed.

Prior to the patient undergoing either angiography, CT scanning, or MR scanning, the mold corresponding to tooth imprints 40 is made by placing mouth portion 39 with dental impression material against the teeth of the patient. Known techniques allow such a mold to be made in about 10 minutes. The mouth portion 39 would then be permanently fixed by adhesive or otherwise to the mount plate 42 (assuming mount plate 42 was not integral with mouth portion 39). The mount plate 42 may be about 3 cm by 6 cm and would have the three holes 44 therein.

A temporary adhesive may then be used to fix marker plate 50 to the mount plate 42 by having posts 52 inserted in the corresponding holes 44. The imaging system 24 images the brain of the patient and senses the position of the at least three markers 54. Three dimensional positions are determined within 0.2 mm throughout the region of interest. Although FIG. 1 has shown the imaging system 24 at the same location as the accelerator 12, it will be appreciated that they could be at separate locations. Instead of using the markers 54

sensed by imaging system 24, one could alternately use the LEDs 38 on the marker plate 46 during the initial imaging and the computer 32 could combine position data relative to the LEDs 38 with the imaging data from imager 24.

During the imaging, the head clamp ring 18 would not necessarily be used, but some patient restraint would normally be used just to remind the patient to hold still for the approximate 30 seconds for complete imaging.

After the diagnostic images have been obtained, a routine stereotactic radiosurgical planning session is conducted. After an acceptable plan has been arrived at the isocenter, or isocenters, of the plan are identified relative to the bite plate markers. This then creates a link between the external reference system, the markers, and the intracranial target.

The patient is then brought into the treatment area. They are positioned and immobilized through the use of comfortable head clamps. At this point the markers used in the diagnostic procedures can be localized through the use of a high precision digitizing probe (not shown).

Instead of using a digitizing probe (not shown) to locate specific marker points on the marker plate such as plate 50, the marker plate 50 could be separated from mount plate 42 and the marker plate 46 attached to mount

plate 42 before mouth portion 39 is placed back in the patient with his or her teeth in registry with the imprints 40. Using marker plate 46, the infrared LEDs 38 are strobed and the camera system 34 identifies the exact position of the plate 46 with respect to six degrees of freedom. In other words, the use of at least three LEDs not in a line allows a precise determination of the position of plate 46 relative to x, y, and z axes and rotation about x, y, and z axes (hence six degrees of freedom).

Since the positions of the markers relative to the intracranial target (such as a brain tumor) are known, it will be known what the positions of the markers should be in order for the target to be at the isocenter of the accelerator 12. Camera system 34 provides the current position of the markers to the computer 32. Comparing the current positions of the markers with the proper positions, the computer 32 computes the appropriate 3 dimensional translations and 3 axis rotations which are required to move the patient to the proper position. For each subsequent treatment after the first radiation treatment, the patient is again placed at the approximate treatment position, the positions of the fiducial markers are determined and the required movements are computed and performed.

Most importantly, the repositioning of the patient to the proper position for treatment does not use the bite plate 26. Instead such repositioning of the patient would use the head clamp ring 18. Therefore, and since
5 the bite plate 26 is not connected to the positioning structure, such repositioning does not put forces or torques on the bite plate 26. Thus, the position locator (bite plate) avoids the misalignments or errors which would otherwise be introduced by having a locator plate
10 fixed to a structure used to reposition the patient.

In order to test the above system, both the known surface contour method as well as the present technique has been implemented in anatomical phantoms. To test out the accuracy and precision of the technique the phantom,
15 a styrofoam manikin, was fitted with a rigid stereotactic frame. The phantom was then scanned and localized and placed into the correct treatment position. The anatomical contours and the bite plate markers were localized. The phantom then underwent a series of
20 precise moves which included both individual translations and rotations and combined moves. These moves were carried out to within 0.1 mm and 0.2 degrees. After each move the contours and bite plate positions were again obtained. The inverse move, the move required to
25 reposition the phantom back to isocenter was then

computed. The results of the experiment showed that the contour method was able to reposition the phantom to within 2 mm of the initial position. The bite plate system was able to accomplish this move to within 0.3 mm.

5 The above increase in precision is nearly an order of magnitude. More importantly the dose gradient routinely obtained in radiotherapy results in a decrease in dose from the 90% intensity to the 50% intensity in approximately 2 mm. This means that tissues at the edge
10 of the targeted volume have a high probability of receiving a subclinical dose for any given fraction. The increased accuracy obtainable with the bite plate system substantially reduces the probability of positional targeting errors.

15 Although the locator is a bite plate in the preferred embodiment, the present invention broadly contemplates other locators which can be place in registry with a portion of a patient.

Advantageously, the bite plate used herein is a non-
20 invasive locator and avoids the discomfort associated with techniques requiring one to put one or more holes in a patient or otherwise remove tissue from a patient. However, the present invention also has applicability to invasive locators which are mechanically independent of

any patient positioning structure (i.e., members used to change or adjust patient position).

Although the present description has assumed the use of three markers such as LEDs 38 or markers 54, more than
5 three could be used and may help provide more accurate positioning information. For example, a fourth LED not in the plane defined by LEDs 38 could provide useful additional information.

Various computer programs may be used to provide the
10 relationship between intracranial or other target points and the markers or LEDs. Likewise, various computer programs may be used to compute the appropriate 3 dimensional translations and 3 axis rotations which are required to move the patient to the proper position.

15 The discussion has so far assumed that one would want to adjust the patient position after re-attachment of the bite plate so that the patient position for a second medical procedure (either diagnostic or remedial) is identical to the initial patient position. However,
20 the present invention also contemplates that the second position could be stabilized offset from the first patient position. In that case, the second medical procedure could use a transformation so that treatment by the probe 20 or imaging by imager 24 could be adjusted to
25 take into account differences between the first patient

position and the second patient position. Because the accelerator 12 movement relative to the patient is normally limited to arcs about two transverse axes, it would be more difficult to adjust for offset between the first patient position and the second patient position, although a radiation head with a greater degree of freedom of movement could allow one to use such a transformation. Using such a transformation technique would allow one to secure the patient position without requiring that the patient position is identical to what it was for the previous treatment. Under such circumstances, a positioner which simply stabilizes the patient position would be sufficient even if the positioner did not provide the ability to move or re-position the patient by way of it. Moreover, if the medical procedure was sufficiently fast, one might be able to avoid use of even a simply position-stabilizing positioner.

Although not shown, one could also have a set of LEDs on the radiation emitting head, collimator, or other part of the linear accelerator 12 and/or the head support. By proper placement of the LEDs to detect any misalignments of the type discussed in the inventors' incorporated by reference patents, the various misalignment correcting mechanisms of those patents would

not be required. Instead of correcting for misalignments using those mechanisms, use of such LEDs on part of the linear accelerator 12 and/or the head support would allow the system to not only compute the translation/rotation
5 of the patient relative to the nominal isocenter of the linear accelerator, but would allow the system to compute the actual isocenter. Thus, the patient could be moved to proper position relative to the actual isocenter. This compensates for any offset between the nominal
10 isocenter (isocenter absent the misalignments) and the actual isocenter.

Although specific constructions have been presented herein, it is to be understood that these are for illustrative purposes only. Various modifications and
15 adaptations will be apparent to those of skill in the art. In view of possible modifications, it will be appreciated that the scope of the present invention should be determined by reference to the claims appended hereto.

What is claimed is:

- 1 1. A medical method comprising the steps, not
2 necessarily in order, of:
 - 3 positioning a patient for a first medical
4 procedure;
5 attaching a mechanically free locator to the
6 patient, the locator having at least 3 LEDs
7 thereon and being in registry with a portion of
8 the patient;
9 using the LEDs a first time to get precise
10 positioning information relative to at least
11 part of the patient;
12 performing a first medical procedure on the
13 patient;
14 after the first medical procedure, removing the
15 locator from the patient;
16 at a later time after the removing of the
17 locator, re-attaching the locator to the
18 patient, the locator again being in registry
19 with the portion of the patient and having an
20 identical orientation relative to the portion
21 of the patient as when the locator was
22 previously attached;
23 after the re-attaching step, using the LEDs a
24 second time to get precise positioning

25 information relative to the at least part of
26 the patient; and
27 after the re-attaching step, performing a
28 second medical procedure on the patient.

1 2. The medical method of Claim 1 wherein the
2 attaching and re-attaching of the locator is non-
3 invasive.

1 3. The medical method of Claim 2 wherein the locator
2 is a bite plate with an external portion connected
3 thereto, and the LEDs are on the external portion, and
4 wherein the attaching includes using a mold of dental
5 impression material to bring the bite plate in registry
6 with teeth of the patient, and wherein the re-attaching
7 uses the mold to bring the bite plate in registry with
8 teeth of the patient with an identical orientation
9 relative to the teeth as when the bite plate was
10 previously attached.

1 4. The medical method of Claim 3 wherein the first
2 medical procedure is an imaging of at least a portion of
3 the patient.

1 5. The medical method of Claim 4 wherein the second
2 medical procedure is a remedial procedure treating at
3 least one problem precisely localized in the first
4 medical procedure.

1 6. The medical method of Claim 5 wherein the second
2 medical procedure uses a probe inserted in the patient
3 for treatment of the patient.

1 7. The medical method of Claim 5 wherein the second
2 medical procedure includes radiotherapy.

1 8. The medical method of Claim 1 wherein both the
2 first and second medical procedures include radiotherapy.

1 9. The medical method of Claim 1 wherein the using
2 of the LEDs the first and second times utilizes a sensing
3 subsystem for sensing the positions of the LEDs, and
4 wherein, before performing the second medical procedure,
5 the patient is positioned using a positioner independent
6 of the locator to secure at least the portion of the
7 patient in a desired position.

1 10. A system for medical procedures, the system
2 comprising:

3 a locator attachable to a patient, having at
4 least 3 LEDs thereon, and having a registration
5 portion for registration with a portion of a
6 patient's body, the registration portion
7 allowing removal of the locator from the
8 patient and re-attachment to the patient with
9 an identical orientation relative to the
10 portion of the patient as when the locator was
11 previously attached, the locator being
12 mechanically free such that a patient is
13 positionable without applying forces to the
14 locator during patient positioning;
15 a positioner independent of the locator and
16 operable to secure at least the portion of the
17 patient in a desired position; and
18 a sensing subsystem for sensing the positions
19 of the LEDs when the patient is in the desired
20 position.

1 11. The system of Claim 10 wherein the locator is
2 non-invasive.

1 12. The system of Claim 11 wherein the locator is a
2 bite plate with an external portion connected thereto,
3 and the LEDs are on the external portion, and the bite

4 plate has dental impression material for fabrication of a
5 mold to bring the bite plate in registry with teeth of
6 the patient, and the mold is operable to bring the bite
7 plate in registry with teeth of the patient with an
8 identical orientation relative to the teeth as when the
9 bite plate was previously attached.

1 13. The system of Claim 10 further comprising a
2 radiotherapy apparatus for applying radiation treatment
3 to a patient, the positioner and sensing subsystem
4 allowing proper positioning of the patient for applying
5 radiation treatment.

1 14. The system of Claim 10 further comprising an
2 imaging subsystem for imaging the patient.

1 15. A medical method comprising the steps, not
2 necessarily in order, of:
3 positioning a patient for a first medical
4 procedure;
5 attaching a locator to a patient, the locator
6 having at least 3 fiducial markers thereon and
7 being in registry with a portion of the
8 patient;

9 using fiducial markers a first time to get
10 precise positioning information relative to at
11 least part of the patient;
12 performing a first medical procedure on the
13 patient;
14 after the first medical procedure, removing the
15 locator from the patient;
16 at a later time after the removing, re-
17 attaching the locator to the patient, the
18 locator again being in registry with the
19 portion of the patient and having an identical
20 orientation relative to the portion of the
21 patient as when the locator was previously
22 attached;
23 after the re-attaching step, using fiducial
24 markers a second time to get precise
25 positioning information relative to the at
26 least part of the patient; and
27 after the re-attaching step, performing a
28 second medical procedure on the patient; and
29 wherein the locator is a bite plate with an external
30 portion connected thereto, and the fiducial markers are
31 on the external portion, and wherein the attaching
32 includes using a mold of dental impression material to
33 bring the bite plate in registry with teeth of the

34 patient, and wherein the re-attaching uses the mold to
35 bring the bite plate in registry with teeth of the
36 patient with an identical orientation relative to the
37 teeth as when the bite plate was previously attached.

1 16. The medical method of Claim 15 wherein the first
2 medical procedure is an imaging of at least a portion of
3 the patient.

1 17. The medical method of Claim 15 wherein the
2 second medical procedure is a remedial procedure treating
3 at least one problem precisely localized in the first
4 medical procedure.

1 18. The medical method of Claim 15 wherein the
2 second medical procedure uses a probe inserted in the
3 patient for treatment of the patient.

1 19. The medical method of Claim 15 wherein the
2 second medical procedure includes radiotherapy.

1 20. The medical method of Claim 15 wherein both the
2 first and second medical procedures include radiotherapy.

1 21. The medical method of Claim 15 wherein the
2 fiducial markers used the first time are objects other
3 than LEDs and the fiducial markers used the second time
4 are LEDs put on the external portion at locations of the
5 objects.

1 22. The medical method of Claim 15 wherein the
2 fiducial markers used the first and second times are
3 LEDs, wherein the using of the fiducial markers the first
4 and second times utilizes a sensing subsystem for sensing
5 the positions of the LEDs, and wherein, before performing
6 each of the first and second medical procedures, the
7 patient is positioned using a positioner independent of
8 the locator to secure at least the portion of the patient
9 in a desired position.

1 23. A system for medical procedures, the system
2 comprising:
3 a locator attachable to a patient, having at
4 least 3 fiducial markers thereon, and having a
5 registration portion for registration with a
6 portion of a patient's body, the registration
7 portion allowing removal of the locator from
8 the patient and re-attachment to the patient
9 with an identical orientation relative to the

10 portion of the patient as when the locator was
11 previously attached, the locator being
12 mechanically free such that a patient is
13 positionable without applying forces to the
14 locator during patient positioning;
15 a positioner independent of the locator and
16 operable to secure at least the portion of the
17 patient in a desired position; and
18 a sensing subsystem for sensing the positions
19 of the fiducial markers when the patient is in
20 the desired position; and
21 wherein the locator is a bite plate with an external
22 portion connected thereto, and the fiducial markers are
23 on the external portion, and the bite plate has a mold to
24 bring the bite plate in registry with teeth of the
25 patient, and the mold is operable to bring the bite plate
26 in registry with teeth of the patient with an identical
27 orientation relative to the teeth as when the bite plate
28 was previously attached.

1 24. The system of Claim 23 further comprising a
2 radiotherapy apparatus for applying radiation treatment
3 to a patient, the positioner and sensing subsystem
4 allowing proper positioning of the patient for applying
5 radiation treatment.

- 1 25. The system of Claim 23 wherein the fiducial
- 2 markers includes three LEDs which uniquely define a
- 3 plane.

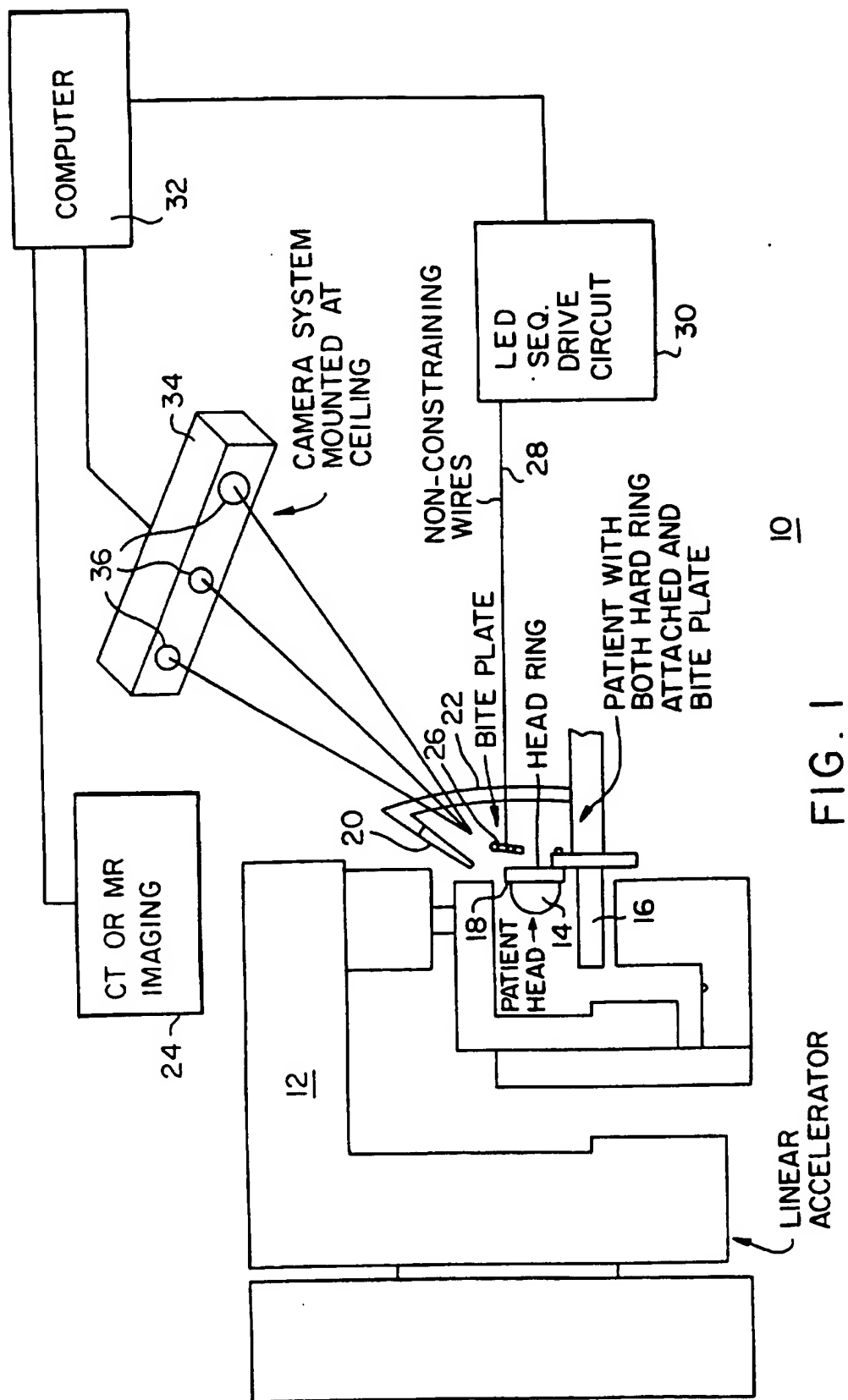


FIG. 1

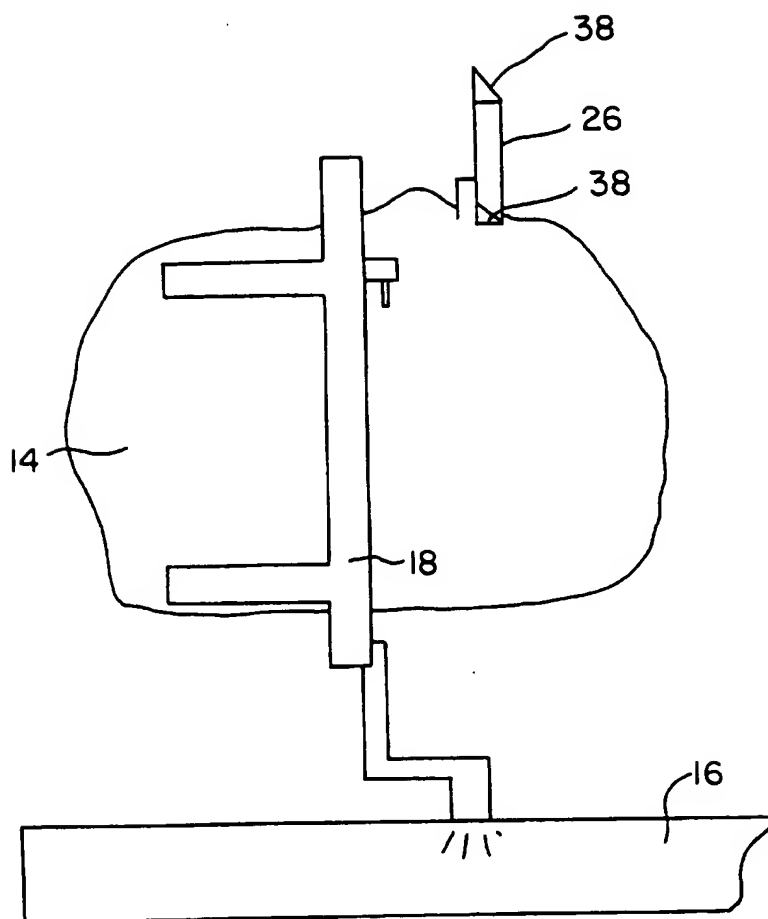


FIG. 2

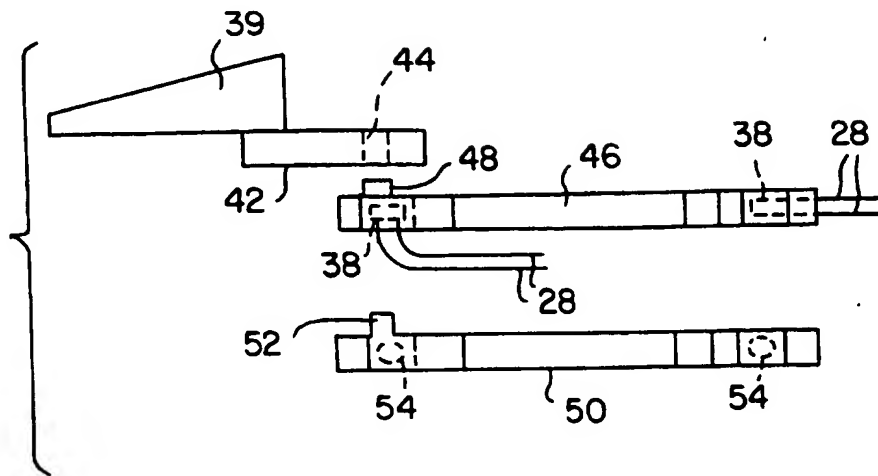
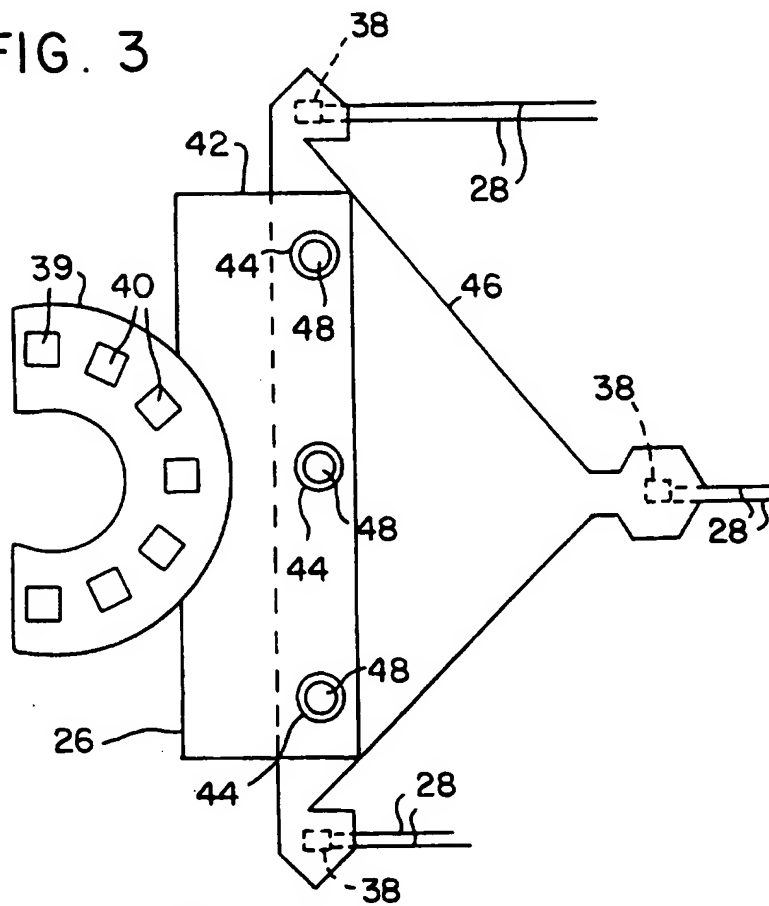


FIG. 4

FIG. 3



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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/06425

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61B 5/05

US CL : 128/653.1

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/653.1; 356/247,248; 378/195,205,206; 606/130

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US, A, 4,971,060(SCHNEIDER ET AL.) 20 NOVEMBER 1990 see entire document	15,16,23 ----- 17-20,24
Y	US, A, 5,383,454(BUCHOLZ) 24 JANUARY 1995 see entire document	17-20,24
A	US, A, 5,090,047(ANGOTTI ET AL.) 18 FEBRUARY 1992 see entire document	1-25
A	US, A, 5,370,117(MCLAURIN JR.) 6 DECEMBER 1994 see entire document	1-25

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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* P	* A	document member of the same patent family

Date of the actual completion of the international search

01 SEPTEMBER 1995

Date of mailing of the international search report

25 SEP 1995

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